IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA, Plaintiff, v. WALMART INC. and WAL-MART STORES EAST, LP, Defendants.	C.A. No. 20-1744-CFC

RESPONSE BRIEF OF THE UNITED STATES
IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS THE COMPLAINT

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NATURE AND STAGE OF PROCEEDINGS

The United States filed a Complaint alleging that Walmart violated the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq*. D.I. 1 ("Compl."). Walmart moved to dismiss. D.I. 27 ("Br.").

SUMMARY OF ARGUMENT

Congress enacted the CSA to protect our nation from the scourge of drug abuse. To further that goal, the CSA and its regulations have long imposed strict rules on the handling of controlled substances. Walmart, as both a pharmacy and a distributor, systematically violated those rules while the opioid crisis raged, contributing to drug abuse nationwide.

The rules Walmart violated are basic and longstanding. They reflect the interwoven legal responsibilities imposed on those authorized to handle controlled substances. Prescribers must adhere to their professional obligations when issuing controlled-substance prescriptions and may issue them only for legitimate medical purposes. 21 C.F.R. § 1306.04(a). To guard against unscrupulous prescribers, pharmacies may not knowingly fill invalid prescriptions, *id.*, and their pharmacists must also adhere to their own professional obligations, *id*. § 1306.06. And to protect against problematic pharmacies, distributors must monitor orders and report suspicious ones to the Drug Enforcement Administration ("DEA"). *Id.* § 1301.74(b). To keep all regulated parties accountable, the CSA provides remedies, including civil

penalties and injunctive relief. 21 U.S.C. §§ 842(c), 843(f).

As the Complaint details, Walmart violated the rules for pharmacies and distributors, despite warnings from its employees that Walmart could face enforcement if its conduct did not change. Its pharmacists—whom Walmart subjected to extraordinary time pressures, understaffing, and impractical restrictions—filled thousands of prescriptions they knew were invalid. Walmart's compliance managers—who oversaw dispensing conduct—knew but withheld critical information from pharmacists, causing them to fill invalid prescriptions. And Walmart's distribution employees failed for years to fix known compliance problems with the company's reporting obligations.

1. **Claim One.** Walmart violated 21 C.F.R. § 1306.04(a) because its pharmacists knowingly filled thousands of invalid controlled-substance prescriptions. Walmart's motion ignores the Complaint's allegations that Walmart pharmacists and compliance managers knew those prescriptions were invalid. Walmart's motion to dismiss part of this claim on the ground that it is purportedly based on a "collective knowledge" theory is procedurally improper and factually and legally baseless.

2. **Claim Two.** Walmart violated 21 C.F.R. § 1306.06 because its pharmacists often failed to adhere to their "usual course of … professional practice" when filling controlled-substance prescriptions. The pharmacists flouted basic professional rules, including by filling prescriptions without resolving obvious red

flags of drug abuse. Walmart's arguments that this misconduct did not violate § 1306.06 contravene well-established law.

Neither is there any merit to Walmart's argument that its misconduct, which violated the CSA's limited authorization for dispensing controlled substances, should not subject it to civil penalties or injunctive relief.

3. **Claim Three.** Walmart violated 21 C.F.R. § 1301.74(b) by failing to report numerous suspicious orders placed by its pharmacies. Walmart was required to report to DEA each time Walmart received an order showing characteristics that made it "suspicious" under § 1301.74(b).

During the relevant period, the CSA imposed civil penalties on registrants who failed to comply with regulatory reporting requirements, including violations of § 1301.74(b).

* * *

Walmart, seeking to evade consequences for its unlawful conduct, makes arguments that are inconsistent with the statute, regulations, and case law. If accepted, Walmart's arguments would render pharmacists rubber stamps. Pharmacies could fill invalid prescriptions while knowingly concealing information from pharmacists and letting their pharmacists flout basic professional obligations. Distributors who failed to report suspicious orders would remain unaccountable. The Court should reject Walmart's arguments in favor of a common-sense reading of the

CSA and its regulations that furthers their purpose of preventing drug abuse.

STATEMENT OF FACTS

I. PHARMACY CONDUCT

A. Walmart knowingly filled invalid prescriptions.

Walmart filled numerous prescriptions that its employees knew, in one or more ways, were invalid. Compl. Part II.

1. Prescriptions issued by known pill-mill prescribers

Walmart filled invalid prescriptions issued by "pill-mill" prescribers—practitioners who routinely issued controlled-substance prescriptions outside the usual course of professional practice or without a legitimate medical purpose. Many such prescribers ultimately faced criminal or administrative sanctions for their egregious conduct. *See* Compl. Part II.B.

It was recognized at certain Walmart pharmacies that invalid prescriptions were being issued by particular pill-mill prescribers. *E.g., id.* ¶¶ 181-83, 187-88, 206, 210-11, 216, 221, 235, 247, 253-55, 258, 300, 335. Pharmacists reported to compliance managers their shared concerns about those prescribers, *e.g., id.* ¶¶ 113, 207, 216, 234-37, 261, 294-96, 304, 342-44, and sometimes highlighted that other pharmacy chains had stopped filling any prescriptions from the prescribers, *e.g., id.* ¶¶ 190, 204-06, 231-35, 273, 280, 317, 324-29, 352-54.

Despite this knowledge, pharmacists at some of those same pharmacies continued to fill prescriptions issued by the known pill-mill prescribers. *E.g., id.*

¶¶ 190, 216-19, 234-39, 244, 272, 290, 296-97, 320-21. This conduct resulted from Walmart policies that turned filling prescriptions into a rushed "battle of seconds"; reduced pharmacy staffing so low that pharmacists complained it was a "safety issue"; and imposed a process for refusing to fill prescriptions so cumbersome that pharmacists could not handle the volume of individuals with prescriptions issued by pill-mill prescribers. *Id.* ¶¶ 20, 115-122, 152, 166-75.

Walmart's compliance managers in the Health and Wellness Division, which oversaw pharmacists from Walmart's Home Office in Arkansas, *id.* ¶ 113, 123, also knew Walmart pharmacists were filling the pill-mill prescribers' invalid prescriptions. These managers—who frequently communicated with pharmacists and imposed restrictions on them—learned of those prescribers in various ways. *Id.* ¶¶ 124-34, 167-74.

Pharmacists warned the compliance managers about specific pill-mill prescribers. *E.g., id.* ¶ 272 (cautioning that a prescriber needed to be "looked into before the DEA comes knocking on our door"). Pharmacists repeatedly requested authority to refuse to fill all prescriptions from known pill-mill prescribers, but the compliance managers rejected those requests—even when told that doing so would lead pharmacists to fill invalid prescriptions. *E.g.*, *id.* ¶¶ 166-174 ("Please help us."), 216-19, 233-39 ("our concerns are falling on deaf ears"), 272-73, 296, 324.

Compliance managers also learned about such prescribers systematically,

through a national dispensing compliance program Walmart adopted in 2011 to resolve a DEA investigation into filling invalid prescriptions. *Id.* ¶¶ 135-40. Under that program, when Walmart pharmacists refused to fill a prescription, they informed compliance managers, who reviewed and compiled that information into spreadsheets. *Id.* ¶¶ 139-47, 178.

Compliance managers discussed the need to share that information about pill-mill prescribers broadly with Walmart pharmacists to prevent individuals from "simply mov[ing] to another location"—*i.e.* pharmacy shopping—where unsuspecting pharmacists might fill these invalid prescriptions. *Id.* ¶¶ 154, 174, 178, 325. The managers nonetheless decided *not* to inform pharmacists about the pill-mill prescribers. *Id.* ¶¶ 149-59, 236-37, 325. Those managers also chose, for years, not to centrally "block" fills of prescriptions issued by known pill-mill prescribers. *Id.* ¶¶ 173-75, 317. As a direct and inevitable result of the compliance managers' conduct, Walmart pharmacists continued to fill invalid prescriptions from these prescribers. *Id.* Part II.B.

2. Prescriptions with obvious red flags

Walmart pharmacists also frequently filled prescriptions with such obvious "red flags"—implausible dosages, drug combinations, and timing—that those pharmacists knew the prescriptions were presumptively invalid. *Id.* Part II.C. In some cases, other Walmart pharmacists already had refused to fill these

prescriptions. *Id.* Part II.D. Many prescriptions showed multiple red flags. *Id.* ¶¶ 366, 382-83, 388-89, 392-93, 395, 402-03, 408, 415.

These red-flag prescriptions were almost certainly invalid in every instance, and pharmacists were trained to recognize them as such. *E.g., id.* ¶¶ 357, 360, 384, 423. The dosages and combinations were known to be dangerous and commonly abused. *Id.* ¶¶ 382, 385, 392, 401-05, 417. Some were for extraordinary dosages, or for quantities that would have an individual taking almost 100 pills daily. *E.g.*, *id.* ¶¶ 373, 412-14.

Walmart's own policies acknowledged that such prescriptions raised red flags and required justifications to fill them. *E.g.*, *id.* ¶¶ 131-34, 363, 423-24. Yet Walmart pharmacists repeatedly filled such prescriptions without resolving their glaring red flags. *Id.* ¶¶ 357, 359, 360-426.

B. Walmart violated basic rules of professional pharmacy practice.

Walmart pharmacists often failed to adhere to basic professional obligations when filling controlled-substance prescriptions.

It is recognized in the pharmacy profession that pharmacists presented with controlled-substance prescriptions must follow essential procedural steps: they must identify any red flags associated with the prescription, determine if those red flags can be resolved, and document any successful resolution. *Id.* ¶¶ 79-88. Walmart's own policies required the same. *Id.* ¶¶ 125-34. But Walmart pharmacists—facing

the pressures described above—frequently filled prescriptions without fulfilling these essential professional obligations. *See id.* Part II.B; *e.g., id.* ¶¶ 122, 152, 173-77, 320-21, 357.

II. DISTRIBUTOR CONDUCT

Walmart, as a distributor, was required to report any suspicious order of controlled substances. Walmart knew which characteristics made a controlled-substance order "suspicious" under 21 C.F.R. § 1301.74(b), and its policies recognized that it was required to monitor its own pharmacies' orders for such characteristics. *E.g., id.* ¶¶ 519.

Walmart received information showing orders with those characteristics. *Id.* ¶¶ 478-526, 546-53, 569-78, 588-90. It flagged some as having those characteristics, yet chose not to report or investigate them. *Id.* ¶¶ 517, 538-83, 610-25. The company knew its order-monitoring system would not identify other suspicious orders and failed to report those as well. *E.g., id.* ¶¶ 569-609.

Walmart's employees knew it needed to address its "non-compliance with … 1301.74(b)" to "avoid DEA enforcement." *Id.* ¶¶ 506-17. But Walmart failed to correct its non-compliance. *Id.* ¶¶ 519-686. As a result, it almost never reported any suspicious orders to DEA. *Id.* ¶¶ 681-96.

ARGUMENT

I. THE COMPLAINT PLAUSIBLY ALLEGES THAT WALMART VIOLATED § 1306.04(a)

Claim One asserts that Walmart violated 21 C.F.R. § 1306.04(a), which provides that a prescription, to be valid, must be "issued for a legitimate medical purpose" by a prescriber "acting in the usual course of his professional practice." Section 1306.04(a) prohibits a "person"—which includes a corporation, *see* § 1300.01(b)—from "knowingly" filling an invalid prescription.

Walmart argues that the Complaint does not plead facts plausibly showing that its pharmacists knew any prescriptions were invalid. Br. 13-17. Walmart also argues that it cannot be liable for filling prescriptions issued by pill-mill prescribers because such liability would necessarily rely on a "collective knowledge" approach to scienter. Br. 6-13.

Both arguments fail. The Complaint alleges extensive facts showing that Walmart pharmacists knowingly filled invalid prescriptions, including those issued by prescribers they knew were pill-mills. The Complaint also does not rely on a "collective knowledge" theory; rather, it alleges that compliance managers knew about and played a role in unlawful dispensing.

At this stage, the Complaint need only allege enough facts to "raise a reasonable expectation" that "discovery will reveal evidence" supporting the government's claims. *Martinez v. UPMC Susquehanna*, 986 F.3d 261, 266 (3d Cir.

2021) (citations omitted). Facts alleged must be construed in the light most favorable to the plaintiff. *See Sweda v. Univ. of Pa.,* 923 F.3d 320, 326 (3d Cir. 2019), *cert. denied*, 140 S. Ct. 2565 (2020). The Complaint need not include "specific facts" beyond those necessary to state a claim, *Schuchardt v. President of the U.S.*, 839 F.3d 336, 347-48 (3d Cir. 2016), and need not plead details of particular violations, *cf. Foglia v. Renal Ventures Mgmt.*, 754 F.3d 153, 156-57 (3d Cir. 2014) (even under Rule 9(b), a plaintiff need not identify particular false claims). Nor must it "preempt … possible explanations" of a defendant's conduct. *Martinez*, 986 F.3d at 267.

Moreover, Congress eased the government's pleading burden in CSA cases. A civil CSA complaint need not allege how a defendant's conduct failed to fit within a statutory "exemption or exception" authorizing the defendant to dispense controlled substances. 21 U.S.C. § 885(a)(1); *United States v. Polan*, 970 F.2d 1280, 1282-83 (3d Cir. 1992) (Alito, J.) (applying rule to indictment).

Those standards are met here.

A. The Complaint plausibly alleges that Walmart pharmacists knowingly filled invalid prescriptions.

The Complaint alleges that Walmart pharmacists filled prescriptions they knew were invalid because of the known practices of the prescriber, obvious problems with the prescription, or both. *See* Compl. Part II.B-D.

For example, pharmacists, who were told by compliance managers that they

had to "hustle from customer to customer" and were "not allowed to blanket refuse to fill for any prescriber," *id.* ¶¶ 116, 237, filled for known pill-mill prescribers despite the concerns, *id.* ¶ 321. Pharmacists felt these prescriptions raised "a risk that keeps me up at night" and created "concern[s] about our jobs" and dangers to "career and family." *Id.* ¶¶ 216, 235-36. Yet, even at pharmacies where specific pill-mill prescribers were identified, some Walmart pharmacists kept filling those prescribers' invalid prescriptions. *E.g., id.* ¶¶ 297, 321.

Walmart pharmacists also filled prescriptions with obvious signs of invalidity, without resolving those red flags. *Id.* ¶ 357. For example, they filled prescriptions for quantities or dosages that were too much for any one person to take and greatly exceeded the highest recommended dose. *Id.* ¶¶ 367, 373, 382, 412-14. They also filled prescriptions that other Walmart pharmacists had refused to fill and reported as not only obviously invalid but dangerous. *Id.* ¶¶ 429, 434.

These prescriptions' invalidity was sufficiently obvious, in one or more ways, that Walmart pharmacists knew it when filling the prescriptions. *See Farmer v. Brennan*, 511 U.S. 825, 844 (1994) (it is proper to "infer knowledge from the obvious"); *Pharmacy Doctors Enters., Inc. v. DEA*, 789 F. App'x 724, 729-31 (11th Cir. 2019) ("red flags" are indicia of a prescription's invalidity); *United States v. Henry*, 727 F.2d 1373, 1379 (5th Cir. 1984) (red flags can alert pharmacist to invalidity of prescriptions "despite their verification by the prescribing physician") ;

accord JM Pharmacy Group, Inc., 80 Fed. Reg. 28667, 28670 (2015); *cf. United States v. Hannigan*, 27 F.3d 890, 893 n.3 (3d Cir. 1994) (knowledge does not require proof of absolute certainty). The pharmacists' training and expertise further show that they would have recognized those prescriptions as invalid. *Cf. Kedra v. Schroeter*, 876 F.3d 424, 442-43 (3d Cir. 2017) (knowledge can be inferred from "the combination of obviousness with … training and expertise").

In response, Walmart speculates about potential (and improbable) facts that were *not* pleaded but *might* show that every filled prescription was valid. Br. 14. It proposes scenarios where its pharmacists *might* have resolved all the prescriptions' red flags, or where all the prescriptions *might* have been ones on which medical professionals would disagree. Br. 15-17.

But Walmart's arguments disregard the pleading standards and fail to view the allegations in the light most favorable to the United States. Walmart cannot ignore the allegations that pharmacists recognized prescriptions as invalid but filled them anyway. Walmart also cannot add its own hypothetical facts. Moreover, even the alternative explanations it conjures up with those facts fail to show that the claimed violations are "implausible." *See Hassan v. City of New York*, 804 F.3d 277, 297 (3d Cir. 2015).

Under a "holistic" view, *Sweda*, 923 F.3d at 331-32, the Complaint more than plausibly alleges that Walmart pharmacists violated § 1306.04(a). *Cf. Cherokee*

Nation v. McKesson Corp., 2021 WL 1200093, at *6 (E.D. Okla. Mar. 29, 2021) (denying motion to dismiss by Walmart; whether pharmacists knew, from red flags, that prescriptions were invalid is a fact issue); *In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 629 n.25 (N.D. Ohio 2020) ("easily conclud[ing]" that similar claims against Walmart "are plausible"), *clarified*, 2020 WL 564273 (N.D. Ohio Sept. 22, 2020) (clarifying different issues). Walmart is liable for those violations as the pharmacists' employer and the entity in whose name the drugs were dispensed.[1]

B. Walmart's request for a "collective knowledge" ruling is flawed.

Walmart argues that the Court should rule that Walmart cannot face liability for filling prescriptions issued by pill-mill prescribers because, in its view, proof of violations relating to those prescriptions would rest on a "collective knowledge" theory that improperly amalgamates unwitting pharmacists' actions with the knowledge of others. Br. 5-13. Walmart is wrong for multiple reasons.

As a threshold matter, "Rule 12(b)(6) doesn't permit piecemeal dismissals of *parts* of claims." *BBL, Inc. v. City of Angola*, 809 F.3d 317, 325 (7th Cir. 2015) (emphasis in original); *FTC v. Nudge, LLC*, 430 F. Supp. 3d 1230, 1246 (D. Utah. 2019) ("many courts have recognized" this limitation); *contrast* Fed. R. Civ. P 56(a). Walmart seeks just such a ruling in arguing that liability cannot attach to

[1] Walmart does not dispute that it may be held liable, based on agency-law principles, for its agents' conduct. Br. 6; *see United States v. Appalachian Reg'l Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1189-90 (E.D. Ky. 2017).

prescriptions issued by pill-mill prescribers.

Walmart's argument also rests on a factual premise inconsistent with the Complaint's allegations. Contrary to Walmart's contention, Br. 5, prescriptions issued by pill-mill prescribers were not all filled by unwitting pharmacists lacking knowledge of the prescriptions' invalidity. As discussed above, some pharmacists filled prescriptions despite personally knowing the prescriber was a pill-mill. Other pharmacists knew prescriptions issued by pill-mill prescribers were invalid not by knowing the prescriber but because the prescriptions had obvious red flags. Some prescriptions had overlapping signs of invalidity. Walmart ignores these allegations in seeking to apply its "collective knowledge" argument to all pill-mill issued prescriptions.

In any event, Walmart's "collective knowledge" argument is flawed. Walmart argues that liability for prescriptions filled by unwitting pharmacists cannot be based on compliance managers' knowledge that the prescribers were pill-mills because those managers were "uninvolved actor[s]" who "played no role in . . . the conduct in question." Br. 7 (citing Restatement (Second) of Agency § 275 cmt. b (1958)). This argument is belied by the Complaint's allegations.

As alleged, compliance managers played a key role in Walmart's dispensing of such prescriptions. They oversaw pharmacists and set dispensing rules that pushed pharmacists to fill prescriptions. They gathered dire reports and data on pill-mill

prescribers but withheld information about those prescribers from other pharmacists. *See supra* pp.5-6; Compl. ¶¶ 154. And—despite knowing the pressures on pharmacists—they rejected pharmacists' requests to blanket refuse those prescribers' prescriptions or to issue "corporate blocks" on those prescribers. *Id.* ¶¶ 166-75. Their conduct directly and predictably led to the filling of invalid prescriptions. *Cf. United States v. City Pharmacy, LLC*, 2016 WL 9045859, at *3 (N.D. W.Va. Dec. 19, 2016) (basing liability for unlawful dispensing on non-pharmacist's conduct).

Established agency principles recognize that corporations can be liable where their agents know important information needed by other agents but knowingly keep those other agents in the dark.[2]

First, corporations are not "immunized" from liability when their employees knowingly withhold information from other employees who need that information to follow the law. For example, in *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908 (4th Cir. 2003), the court upheld liability for a corporation when one employee withheld important information from another who, as a result, made a false certification. The court explained that holding otherwise

[2] As Walmart observes, Br. 7, the Supreme Court cited one Restatement agency principle in *Staub v. Proctor Hospital*, 562 U.S. 411 (2011). But the Court did not conclude that it was the *only* relevant principle, or even a valid one. The Court observed that the law is "not so clear," cited different principles, and found it "unnecessary … to decide what the background rule of agency law may be." *Id.* at 418.

would allow corporations to "immuniz[e]" themselves from liability by "establish[ing] segregated 'certifying' offices." *Id*. at 919. The court expressly disclaimed reliance on a "collective knowledge" theory: it did not "cobbl[e] together pieces of 'innocent' knowledge to find the requisite scienter," but relied on the knowledge of the employee who withheld the information. *Id.* at 918 n.9; *cf. Grand Union Co. v. United States*, 696 F.2d 888, 889 (11th Cir. 1983) (corporation liable where employees knew another, unsuspecting employee was falsely certifying food stamps).

Second, established agency principles similarly recognize that a principal cannot evade liability when its agents engage in conduct they expect will cause others to engage in wrongful acts. "[T]raditional agency principles" impose liability where "the agent intended and was the proximate cause of the adverse result," even when another person took the ultimate action. *Menaker v. Hofstra Univ.*, 935 F.3d 20, 38 (2d Cir. 2019); *cf.* Restatement (Second) of Agency § 275 cmt. b, illus. 4 (1958) (person who causes innocent agent to make false representation is liable for fraud if the person "intended" the result); Restatement (Third) of Agency § 5.03 cmt. d(7) (2006) (principal may be liable in "appropriate circumstances" where agent with knowledge does not engage in the conduct at issue but "ratifies" or "directs" it).

An agent's "intention" is shown by the expected consequences. *See Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005) (person is

"presumed to intend the natural consequences of his acts") (citations omitted); Restatement (Second) of Torts § 8A cmt. b (1965) (person who knows consequences of his act are "substantially certain" is "treated by the law as if he had in fact desired" the result). Here, the compliance managers knew it was substantially certain that their conduct would lead pharmacists to fill invalid prescriptions; indeed, those managers were told as much. *E.g.,* Compl. ¶¶ 153-56, 173-74.

Agency principles further recognize that a corporation can be liable based on a failure to share information with agents if the failure violates a regulatory duty. *See* Restatement (Third) of Agency § 5.03 cmt. d(7)(g) (courts have imputed knowledge where a principal has a "duty to transmit all material facts to the agent" and "regulatory objectives would be undermined were principals to limit disclosure of material facts to their agents"). This principle was applied specifically to pharmacies by the court presiding over the opioid multidistrict litigation: given their duties under the CSA, pharmacies "cannot collect data as required … but then *do nothing* with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled." *Opiate Litig.*, 2020 WL 5642173, at *2 (N.D. Ohio Sept. 22, 2020) (emphasis in original). Walmart had those same CSA duties—*plus*, under its 2011 agreement with DEA, specific obligations to operate a dispensing-compliance program.

Third, the doctrine of willful blindness prevents parties from escaping

knowledge-based liability by shielding themselves from facts. *See Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011); *United States v. Khorozian*, 333 F.3d 498, 508 (3d Cir. 2003) (doctrine "allows the jury to impute the element of knowledge to the defendant") (citations omitted); *Opiate Litig.*, 2020 WL 5642173, at *2 (a pharmacy may not be "deliberately ignorant or willfully blind regarding its own prescription information"). Walmart's compliance managers deliberately shielded pharmacists from critical information.

In sum, even setting aside the allegations that pharmacists filled prescriptions they knew were invalid, these principles permit also holding Walmart liable under § 1306.04(a) based on its compliance managers' authority, knowledge, and conduct. While discovery will illuminate the managers' exact knowledge and roles, the Complaint sufficiently alleges facts to "raise a reasonable expectation" that "discovery will reveal evidence" making the application of these agency principles appropriate here. *Martinez*, 986 F.3d at 266. No more is needed at this stage. *See Karon v. CNU Online Holdings, LLC*, 2019 WL 3202822, at *2 (N.D. Ill. July 16, 2019) (because agency principles are highly factual, plaintiffs need not plead "evidentiary facts").

II. THE COMPLAINT PLAUSIBLY ALLEGES § 1306.06 VIOLATIONS, WHICH MAY BE ENFORCED THROUGH CIVIL PENALTIES AND INJUNCTIVE RELIEF

Claim Two asserts that Walmart, through its pharmacists, violated 21 C.F.R. § 1306.06, which requires pharmacists to adhere to the "usual course of professional practice" when dispensing controlled substances. As the Complaint alleges, professional practice standards require a pharmacist presented with a controlled-substance prescription to identify any red flags raised by the prescription, seek to resolve them, and document that resolution. Compl. ¶¶ 79-88. Walmart's own policies required pharmacists to take these steps. *Id*. ¶¶ 127-34. But Walmart pharmacists—subjected to severe time pressures and restrictions on their authority to blanket refuse prescriptions—frequently failed to take those steps. *E.g., id.* ¶¶ 112, 122, 173-74, 357-58.

A. The Complaint plausibly alleges § 1306.06 violations.

Walmart argues that its alleged conduct cannot violate § 1306.06 because "the proper standard" for determining what conduct falls outside the "usual course of professional practice" should be whether a pharmacist "act[ed] as a drug 'pusher' operating for 'personal profit.'" Br. 27. Walmart is wrong.

The CSA's "usual course of professional practice" standard is well established, including in the pharmacy context. *See United States v. Moore*, 423 U.S. 122, 140-42 (1975) (upholding physician's conviction for failing to follow "the usual course of professional practice" when issuing methadone prescriptions); *United States v.*

Ludwikowski, 944 F.3d 123, 136 (3d Cir. 2019) (affirming pharmacist's conviction for failing to follow "professional practice in the pharmacy field"), *cert. denied*, 141 S. Ct. 872 (2020). The "usual course of professional practice" refers to the profession's "generally accepted" practices. *United States v. Birbragher*, 603 F.3d 478, 485-86 (8th Cir. 2010). Courts routinely accept testimony from expert witnesses on the "usual course of professional practice." *See United States v. Shaker*, 827 F. App'x 204, 207-08 (3d Cir. 2020); *United States v. Bado*, 764 F. App'x 284, 286 (3d Cir. 2019); *United States v. Rottschaefer*, 178 F. App'x 145, 150 (3d Cir. 2006).[3] A "case-by-case analysis of evidence" is required. *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995); *accord Farmacia Yani*, 80 Fed. Reg. 29053, 29062 (May 20, 2015) (showing § 1306.06 violations requires establishing "the standards of pharmacy practice … through … expert testimony" or otherwise).

Here, the Complaint alleges that Walmart pharmacists violated § 1306.06 by violating generally accepted professional obligations when filling controlled-substance prescriptions. Under the pleading standards and law discussed above, this is sufficient.

Walmart's contrary arguments fail. *First*, the professional practice standard does not prohibit only "drug pusher" behavior. Br. 27. Rather, practitioners who

[3] Contrary to Walmart's implication, Br. 26-27, the *Rottschaefer* court did not hold that malpractice can never meet this standard, 178 F. App'x at 146-48.

depart from the "usual course" of professional practice were "subject to the same penalties as street pushers." *Moore*, 423 U.S. at 139 (interpreting the Harrison Act); *United States v. Ruan*, 966 F.3d 1101, 1168 (11th Cir. 2020) ("[n]umerous courts" have rejected "drug pusher" argument).

Second, Walmart contends that § 1306.06 cannot look to professional practice standards lest § 1306.06 become "superfluous" to § 1306.04. Br. 24-25. Not so. Those regulations address the standards of different professions: pharmacists in § 1306.06 and prescribers in §1306.04(a). Two professions, two regulations. Section 1306.06 requires pharmacists to adhere to the professional practice of *pharmacists*. In contrast, section 1306.04(a) requires *prescribers* to comply with their own "usual course of … professional practice" when issuing controlled-substance prescriptions. When the prescriber issues a prescription not meeting their professional standard, that prescription must not be filled, although the regulation clarifies that the person filling such a prescription faces penalties only if the person knew it was invalid.

Sections 1306.04(a) and 1306.06 thus operate differently. Pharmacists might disregard their own professional obligations and take none of the essential procedural steps required of pharmacists when filling prescriptions (violating § 1306.06) but the prescriptions might happen to be valid. Or a pharmacist filling a prescription might take those essential procedural steps despite otherwise knowing the prescription is

invalid (violating § 1306.04(a)). That some conduct might violate both standards is permissible redundancy. *See Rimini St., Inc. v. Oracle USA, Inc.*, 139 S. Ct. 873, 881 (2019) (redundancy in statutes is "hardly unusual" and is "[s]ometimes the better overall reading"). Moreover, "superfluity" is an interpretive principle for reading texts, not changing them. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 236 (2011) (desire to avoid superfluity "does not prescribe that a passage … does not mean what it says"); *Lamie v. U.S. Tr.*, 540 U.S. 526, 536 (2004) (where "the text is plain," "the rule against surplusage is … inappropriate"). Walmart's "superfluity" argument thus cannot change the standard that § 1306.06's text clearly imposes.

Third, Walmart argues that whether it violated § 1306.06 should not be determined by professional standards. Br. 25-26. But Congress understood that the meaning of "professional practice" depends on professional standards. *See Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (Attorney General cannot define "professional practice" for physicians because the "structure and operation of the CSA presume and rely upon a functioning medical profession"). Expert testimony can address whether particular professional obligations are generally accepted.

Fourth, Walmart suggests that the "professional practice" standard might be uncertain. Br. 26. But courts have uniformly rejected vagueness challenges to that standard, even in the criminal context. *See Birbragher*, 603 F.3d at 484-89 (citing cases).

B. Walmart faces civil penalties and injunctive relief for its § 1306.06 violations.

Walmart argues that civil penalties and injunctive relief are not available to address violations of § 1306.06's professional-practice standard. In its view, those remedies are available only for dispensing "without a prescription," not for dispensing outside the course of professional practice. Br. 20. This argument misunderstands the CSA's text, is inconsistent with its purpose, and would lead to absurd results.

21 U.S.C. § 829 authorizes dispensing of controlled substances either (a) directly to users by practitioners that are not pharmacies, or (b) by other practitioners (*i.e.*, including pharmacies) if pursuant to a prescription. *E.g.*, § 829(a) ("Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in Schedule II … may be dispensed without [a prescription]"). It is undisputed that a violation of § 829 can give rise to civil penalties and injunctive relief. Br. 20.

Courts have determined that § 829 defines a limited authorization—*allowing* a "practitioner" to "dispense" a controlled substance, which would otherwise violate the CSA. *See United States v. Bansal*, 663 F.3d 634, 656 (3d Cir. 2011) (by permitting dispensing by authorized professionals, § 829 operates as "[a]n exception to [the CSA's] blanket prohibition"); *United States v. Khan*, 989 F.3d 806, 824 (10th Cir. 2021) (Section 829 is an "authorization exception" that "permits a registered

practitioner to dispense a controlled substance with a 'prescription'"); *United States v. Tobin*, 676 F.3d 1264, 1274 (11th Cir. 2012) ("Section 829 … authorizes 'practitioner[s]' to dispense … with a 'prescription.'"), *overruled on other grounds by United States v. Davila*, 569 U.S. 597 (2013).

The scope of § 829's "key statutory terms" of "dispense," "practitioner," and "prescription" are "defined either by statute … or by regulation." *Tobin*, 676 F.3d at 1274. The CSA limits dispensing by *practitioners*: "'[D]ispense' means to deliver a controlled substance to an ultimate user [directly or] pursuant to [a] lawful order [*i.e.*, a prescription], including … prescribing …. The term 'dispenser' means a practitioner who so delivers a controlled substance to an ultimate user" 21 U.S.C. § 802(10). The CSA defines "practitioner," in turn, to include a "pharmacy" and recognizes that the pharmacy (and its pharmacists) may "dispense … a controlled substance in the course of professional practice." *Id.* § 802(21).

A person is not an authorized "practitioner" (who can "dispense") except when acting within "the course of professional practice." In *Moore*, the Supreme Court determined that this "professional practice" limitation "is made explicit" because the CSA defines "practitioner" as limited to the "course of professional practice …." 423 U.S. at 140-41; *id*. at 142 (a practitioner's authorization "is limited to the

dispensing … of drugs 'in the course of professional practice'").[4] This "professional practice" limitation on all "practitioners" thus restricts the scope of the dispensing authorization provided in 21 U.S.C. § 829. *Cf. Bansal*, 663 F.3d at 657 (noting "the exception that § 849 [*sic*: 829] affords" to permit dispensing pursuant to prescriptions "in the usual course").

In turn, section 1306.06 incorporates this definitional "professional practice" limitation into the dispensing rules for pharmacists. While Walmart notes that § 1306.06 itself "contains no reference to 829," Br. 21, it ignores that § 1306.06 falls within Part 1306, which governs the scope of § 829's dispensing authorization: "Rules governing the issuance and filing of prescriptions pursuant to … 21 U.S.C. § 829… are set forth … specifically by the sections of this part." 21 C.F.R. § 1306.01; *see United States v. City Pharmacy, LLC*, 2017 WL 1405164, at *3 (N.D. W. Va. Apr. 19, 2017) (Part 1306 "provide[s] the scope of § 829"). Section 1306.06 thus "govern[s]" the scope of § 829, including by explicitly incorporating the CSA's "professional practice" limitation for pharmacists.[5]

Walmart acknowledges that regulatory violations can "imply a violation" of

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[4] The court of appeals "suggested that Dr. Moore could be prosecuted … for having violated … § 829," but he was prosecuted under a different provision. 423 U.S. at 135-36.

[5] Congress has recognized that regulations govern dispensing under § 829. *See* 21 U.S.C. § 829(e)(1), (3)(B) (2008) (clarifying that new subsection (e) would not affect regulations governing dispensing).

§ 829 and identifies § 1306.04(a) as "an example." Br. 20. *See Gonzales*, 546 U.S. at 257 (recognizing that § 1306.04(a) incorporates the CSA's "professional practice" limitation). Section 1306.06 obviously incorporates the same "professional practice" limitation on dispensing under § 829: pharmacists who fill controlled-substances prescriptions—just like prescribers who issue them—must comply with their own "usual course of … professional practice."

Practitioners who violate *either* "professional practice" requirement (in § 1306.04(a) or § 1306.06) thus violate § 829's dispensing authorization. *See United States v. Iriele*, 977 F.3d 1155, 1169 (11th Cir. 2020) (§ 829 is an "exception" that "allows pharmacists to fill [prescriptions] …. Regulations specify when the exception applies and when it doesn't"); *Heartland Pharmacy, Inc. v. Rosen*, 2021 WL 650350, at *3 n.4 (S.D. Fla. Feb. 18, 2021) (§ 842(a)(1), which prohibits dispensing in violation of § 829, "is defined … by 21 C.F.R. §§ 1306.04(a), 1306.06"); *United States v. Cap Quality Care, Inc.*, 486 F. Supp. 2d 47, 50-53 (D. Me. 2007) (imposing civil penalties for § 829 violations where dispensing violated various regulations).

Walmart's contention that § 829 only requires patients to have valid prescriptions (Br. 21) ignores this framework and leads to an unreasonable reading of § 829. In Walmart's view, if a pharmacist acted outside the course of professional practice—such as by leaving controlled substances unattended on a counter with a

sign telling patients to retrieve their own medication—this conduct would *comply with* § 829's dispensing authorization so long as the patients happened to have valid prescriptions. Such conduct cannot reasonably be viewed as dispensing pursuant to a prescription by a practitioner acting in the course of professional practice, which is what § 829 authorizes.

Walmart next suggests that § 1306.06 violations should result only in "administrative" sanctions—termination of the pharmacy's registration. Br. 22. But deregistration is a draconian approach that, Walmart admits, would "destroy a pharmacy." Br. 19. The Attorney General is not required to pursue deregistration rather than penalties. *Moore*, 423 U.S. at 138 n.15. Nor must the Attorney General select only one enforcement tool. 21 U.S.C. § 824(c) (deregistration "shall be independent of and not in lieu of … other proceedings").

Congress provided civil penalties and injunctive relief as tools to hold accountable those who violate the CSA's statutory authorization to dispense controlled substances. 21 U.S.C. §§ 842(a)(1), (c)(1); 843(f). Walmart suggests that unintentional violations should not lead to civil penalties. Br. 25-26. But Congress chose otherwise. *See United States v. Green Drugs*, 905 F.2d 694, 697-98 (3d Cir. 1990) (rejecting objection that 21 U.S.C. § 842 would "hold virtually any pharmacy liable for the most minor infraction," explaining that this "is a consequence that Congress likely accepted").

Walmart's reading of the CSA also would lead to bizarre results. Pharmacists employed by registered pharmacies, unlike the pharmacies, need not register with DEA. 21 U.S.C. § 822(c)(1). Accordingly, under Walmart's approach, for pharmacists who violated § 1306.06's professional-practice standard, the *sole* remedy would be *criminal* prosecution. This absurd result would be inconsistent with the CSA's graduated-penalty structure.

III. THE COMPLAINT PLAUSIBLY ALLEGES § 1301.74(b) VIOLATIONS, WHICH MAY BE ENFORCED THROUGH CIVIL PENALTIES

When Walmart distributed controlled substances to its own pharmacies, it was obligated to monitor its pharmacies' orders and identify "suspicious orders," which "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). It was then required to timely report those orders to DEA. *Id*. (registrant "shall inform" DEA of suspicious orders "when discovered").

The Complaint alleges extensive facts plausibly showing that Walmart violated § 1301.74(b) for years by shirking its duty to report suspicious orders. Compl. Part III. Walmart knew that many orders it received had characteristics making those orders "suspicious" as defined by § 1301.74(b). *Id.* ¶¶ 478-526, 546-53, 569-78, 588-95. Walmart flagged some of those orders but chose not to report them. *E.g., id.* ¶¶ 538-45, 559-68, 600-05, 610-21. It also knew its order-monitoring

system failed to flag other suspicious orders but ignored its obligation to report them. *E.g., id.* ¶ 569-625. Compliance managers acknowledged Walmart needed to fix these problems to "avoid DEA enforcement as a result of non-compliance with … 1301.74(b)." *Id.* ¶ 513. But Walmart left the problems unaddressed, rarely reporting suspicious orders from its own pharmacies and failing to address the concerns those orders raised about its pharmacies. *Id.* ¶¶ 681-94.

The Complaint plausibly alleges that Walmart violated § 1301.74(b)'s reporting requirement, and those violations make Walmart subject to civil penalties.

A. Section 1301.74(b) requires suspicious orders to be reported promptly, not at the distributor's discretion.

Walmart contends that § 1301.74(b) requires reporting a suspicious order only if *a registrant itself* opts to "identify" the order as suspicious, Br. 31-32, but Walmart misreads § 1301.74(b).

Section 1301.74(b) does not provide that registrants can avoid reporting orders that qualify as suspicious under that provision's definition by declining to identify them as such. By requiring reports "when discovered by the registrant," § 1301.74(b) requires *promptness* in reporting, without delay, once registrants receive an order showing characteristics meeting the definition.

Expressly rejecting the interpretation of § 1301.74(b) that Walmart advocates here, DEA has observed that, if only those orders a registrant *deems* to be "'actually discovered' [were] subject to reporting," this approach would "incentivize registrants

to turn a blind eye." *Masters Pharms., Inc.*, 80 Fed. Reg. 55418, 55477 (Sept. 15, 2015), *pet. for rev. den.,* 861 F.3d 206 (D.C. Cir. 2017). DEA explained that § 1301.74(b)'s reporting duty instead arises "where the registrant has obtained information that an order is suspicious." *Id.* at 55478; *see Southwood Pharms., Inc*., 72 Fed. Reg. 36487, 36501-02 (July 3, 2007) (distributor "repeatedly violated" § 1301.74(b) by "failing to report suspicious orders" when it received orders with information showing they were suspicious).

DEA's interpretation of § 1301.74(b) accords with the regulation's text and purpose. Even if the meaning of § 1301.74(b) were ambiguous, DEA's position warrants deference. It is reasonable, reflects DEA's "considered judgment" and "official position," and addresses a reporting matter within DEA's "substantive expertise." *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2414-17 (2019).

Thus, Walmart had to report each order it received showing characteristics that made it suspicious under § 1301.74(b). The Complaint plausibly alleges that Walmart failed to do that. *Cf. Opiate Litig.*, 2019 WL 3917575, at *7 n.8 (N.D. Ohio Aug. 19, 2019) ("the timing of when [a suspicious order] is 'discovered'" depends on the circumstances). When Walmart's monitoring system identified a "potentially 'suspicious' order," Walmart fulfilled the order without reporting the discovery.[6]

[6] Because the Complaint alleges that Walmart flagged orders with suspicious characteristics but failed to report them, the Complaint plausibly alleges violations even under Walmart's erroneous reading of § 1301.74(b).

E.g., Compl. ¶¶ 611-18. For example, for suspiciously large orders, Walmart unilaterally "cut" their size without reporting them. *E.g.*, *id*. ¶¶ 559-568, 665-69. These and other examples in the Complaint do not show Walmart's total compliance with § 1301.74(b), but its abject failure. *E.g.,* Compl. ¶¶ 681-86 (Walmart reported infinitesimal proportion of orders).

B. Walmart is subject to civil penalties for violating § 1301.74(b)'s reporting requirement.

Walmart argues that violations of § 1301.74(b)'s reporting requirement are exempt from civil penalties. Br. 29-31. Proper statutory interpretation, however, shows that such violations are subject to civil penalties as negligent failures to submit required reports under 21 U.S.C. § 842(a)(5), violations of which are subject to civil penalties. The CSA's history and purpose also support reading § 842(a)(5) to cover reports required by regulation. The CSA was crafted to strengthen the laws regarding the monitoring of controlled substances, and part of this effort "to monitor the drug transactions of registrants" included creating the civil penalties for violating § 842(a)(5). *Green Drugs*, 905 F.2d at 698. Congress intended that the details of this monitoring would be implemented through regulations.

Section 842(a)(5) broadly makes it "unlawful for any person … to refuse or negligently fail to make, keep or furnish any record, report, notification, declaration, order or order form, statement, invoice or information required under this subchapter or subchapter II of this chapter." For the source of the covered reporting

requirements, Congress did not cross-reference specific statutory provisions; rather, it used the phrase "under this title" (now "this subchapter or subchapter II") to encompass reporting requirements on any matter covered by the CSA. The laundry list of covered reports, which even includes a catch-all to cover "any … information required" under the CSA, reflects the provision's intended expansiveness.

Focusing on the phrase "under this subchapter," Walmart argues that the word "under" means § 842(a)(5) covers only reports the statute itself directly mandates. Br. 29-30. But the Supreme Court has held that the word "under" by itself cannot determine whether a statutory provision refers to regulations because "under" is a "chameleon" and there are "hundreds of statutory provisions in which regulations are described as being issued 'under' a statute." *Kucana v. Holder*, 558 U.S. 233, 245 & n.12 (2010) (the "diverse renderings of 'under,' standing alone, do not equip us to resolve this case"). The word "under" instead "must draw its meaning from its context." *Id*. at 245 (citations omitted). Here, a proper examination of the "statutory context, structure, history, and purpose," *Abramski v. United States*, 134 S. Ct. 2259, 2267 (2014), supports interpreting § 842(a)(5) to include reports required by regulation.

The CSA's structure also shows that Congress expected registrants to be subject to requirements established by regulation. The CSA broadly authorized the Attorney General to promulgate regulations relating to "registration," 21 U.S.C.

§ 821, and as "appropriate for the efficient execution" of the Attorney General's functions, *id*. § 871(b). Congress described various anticipated regulations as appearing "under" the CSA. *See id.* §§ 811(a) ("Rules of the Attorney General under this subsection"), 822(g) ("regulations under this section"), 825(c) ("shall prescribe regulations under section 353(b)"), 827(a)(1) ("regulations prescribed under this section"). The Attorney General promptly adopted such regulations, including § 1301.74. 36 Fed. Reg. 7776 (Apr. 24. 1971).

Analyzing § 842(a)(5)'s context requires examining surrounding provisions that were "enacted simultaneously." *Kucana*, 558 U.S. at 248; *Esquivel-Quintana v. Sessions*, 137 S. Ct. 1562, 1570 (2017) ("Surrounding provisions … guide our interpretation"); *Yates v. United States*, 574 U.S. 528, 536 (2015) (agreeing with "a contextual reading" considering "related provisions enacted at the same time"). Here, the surrounding provisions enacted simultaneously with § 842—*i.e.*, §§ 841 and 843—confirm that Congress used "the subchapter" expansively to include the anticipated regulations.

Section 841 begins by providing that conduct is unlawful "[e]xcept as authorized by this subchapter." If "subchapter" in § 841(a) were read to refer to only the *statute's* provisions and not regulations, then conduct the Attorney General has authorized by regulation as lawful would not be "authorized by this subchapter" and would instead be subject to criminal prosecution. That construction would deprive

the Attorney General of the authority to authorize, through regulations, areas of lawful conduct, thus undermining the broad regulatory authority Congress provided. *See* 21 U.S.C. §§ 821, 871. Indeed, the Attorney General has authorized, in several regulations, conduct not specifically authorized by statutory provisions. *See, e.g.*, 21 C.F.R. §§ 1301.12(b), 1301.23-24, 1301.26, 1307.03, 1307.11, 1317.13. The better reading of 21 U.S.C. § 841 is that Congress contemplated conduct "authorized by this subchapter" to include conduct authorized by regulations adopted under the subchapter.

21 U.S.C. § 843, in turn, uses "under this subchapter" in a way that supports reading it to encompass regulations. With language similar to § 842(a)(5)'s terms, § 843(a)(4)(A) prohibits providing false material information in "any application, report, record or other document required to be made, kept, or filed under this subchapter or subchapter II." There is no indication that Congress meant that falsity was prohibited in statutorily-required reports but *permitted* in reports required by regulation. Nor have courts read § 843(a)(4)(A) that way; they have upheld convictions under § 843(a)(4)(A) where the falsity appeared in information required by regulation. *See United States v. Tull-Abreu*, 921 F.3d 294, 304 & n.6 (1st Cir. 2019); *United States v. Lartey*, 716 F.2d 955, 964-65 (2d Cir. 1983). Section 843, like § 841, thus supports construing § 842(a)(5)'s reference to reporting requirements "under this subchapter" as applying to requirements imposed by regulation.

Disregarding the required focus on contemporaneously-adopted surrounding provisions, Walmart points to § 829(f)(1), which permits partial filling of prescriptions "in accordance with this subchapter, regulations prescribed by the Attorney General, and State law." Walmart claims this "contrast" shows that Congress intentionally omitted the word "regulations" from § 842(a)(5). Br. 29. But § 829(f) was not enacted until 2016 and sheds no light on Congress's intent in 1970. No similar "contrast" can be found in § 842(a)'s original eight subsections: none refer to "regulations." United States Statutes at Large, Pub. L. No. 91-513, 84 Stat. 1236, 1262 (1970).[7]

Walmart implies that, before 2018, it was presumed that § 842(a)(5) did not reach reports required by regulation. Br. 30-31. Not so. Well before the SUPPORT Act, courts imposed penalties under § 842(a)(5) for violations of regulatory requirements. *United States v. Stidham*, 938 F. Supp. 808, 814 (S.D. Ala. 1996); *United States v. Lerner*, No, 85 C 7593, 1986 WL 8471, at *1 (N.D. Ill. July 30, 1986). DEA also warned that violations of § 1301.74(b) could lead to civil penalties under § 842(a)(5). *See Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008*, 74 Fed. Reg. 15596, 15609 n.47 (Apr. 6, 2009) (distributors "must report to DEA … suspicious orders … in accordance with 21

[7] Walmart also mentions 21 U.S.C. § 828(a), Br. 29, but that provision does not use the word "subchapter" or other language similar to § 842(a)(5) and thus does not illuminate § 842(a)(5)'s meaning.

CFR 1301.74(b). Failure to comply … may… result in civil monetary penalties").

Legislators likewise understood, before the SUPPORT Act, that civil penalties could be imposed when registrants failed to report suspicious orders. *See, e.g.*, 164 Cong. Rec. S2657, 2680 (daily ed. May 15, 2018) (Sen. Feinstein) (the bill "increases existing civil fines for … distributors who fail to report suspicious orders"); 164 Cong. Rec. S6159, 6173 (daily ed. Sept. 17, 2018) (Sen. Cantwell) ("[o]ur legislation increases the civil penalties" for "the law that is already on the books about the reporting of suspicious distribution").

In any event, Walmart's argument—that this Court should look to a 2018 law to determine what a 1970 law meant before 2018—lacks merit. The SUPPORT Act did not purport to define the law retroactively or clarify what Congress contemplated in 1970. *See Almendarez-Torres v. United States*, 523 U.S. 224, 237 (1998) ("These later enacted laws, however, are beside the point. They do not declare the meaning of earlier law."); *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) ("subsequent legislative history is a 'hazardous basis for inferring the intent of an earlier' Congress") (citations omitted).

Section 842(a)(5) is properly read to cover violations of § 1301.74(b)'s reporting requirement. Because, as the Complaint plausibly alleges, Walmart violated that requirement, it is subject to civil penalties. 21 U.S.C. § 842(c)(2).

CONCLUSION

The Court should deny Walmart's motion, and this case should proceed.

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WORD COUNT CERTIFICATION

The undersigned hereby certifies that the foregoing brief contains 8,000 words (exclusive of the cover page, table of contents, table of authorities, and signature block) in Times New Roman 14-point font, counted using Microsoft Word's word count feature.

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